Sheet <u>1</u> of <u>4</u>

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 039US1	Application No. 10/759,811	
1	losure Statement plicant	Applicant Patrick Miles et al.		
(Use several sheets if necessary) (37 CFR §1.98(b))		Filing Date January 16, 2004	Group Art Unit 3732	

	U.S. Patent Documents						
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	1	5,171,279	12/15/1992	Mathews			
	2	5,792,044	8/11/1998	Foley et al.			
	3	5,944,658	8/31/1999	Koros et al.			
	4	6,095,987	8/1/2000	Schmulewitz			
	5	6,152,871	11/6/2000	Foley et al.			
	6	6,468,207	10/22/2002	Fowler Jr.			
_	7	6,524,320	2/25/2003	DiPoto			
	8	6,847,849	1/25/2005	Mamo et al.			
	9	6,945,933	09/20/2005	Branch			
	10	7,261,688	8/28/2007	Smith et al.			
	11	7,582,058	9/1/2009	Miles et al.			
	12	2003/0149341	8/7/2003	Clifton			
,,,,,,,,,	13	2006/0025703	2/2/2006	Miles et al.			
	14	2006/0069315	3/30/2006	Miles et al.			
	15	2007/0198062	8/23/2007	Miles et al.	i		
	16	2008/0058606	3/6/2008	Miles et al.			
	17	2008/0097164	4/24/2008	Miles et al.			
	18	2009/0124860	5/14/2009	Miles et al.			
	19	2009/0192403	7/30/2009	Gharib et al.			
V	20	2009/0204016	8/13/2009	Gharib et al.			

	Foreign Patent Documents or Published Foreign Patent Applications							
Examiner	Desig.	Document	Publicati	Country or			Trans	lation,
Initial	ַ חו	Number	on Date	Patent Office	Class	Subclass	Yes	No
	21	EP 0 972 538	1/19/2000	EPO				
	22	WO 00/38574	7/6/2000	WIPO				
,,,,,,,	23	WO 01/37728	5/31/2001	WIPO				
	24	WO 02/054960	7/18/2002	WIPO				

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Sheet <u>2</u> of <u>4</u>

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	Foreign Patent Documents or Published Foreign Patent Applications							
Examiner	Desig.	Document	Publicati	Country or			Trans	lation,
Initial	l ID	Number	on Date	Patent Office	Class	Subclass	Yes	No
	25	WO 03/005887	1/23/2003	WIPO				
V	26	WO 06/066217	6/22/2006	WIPO				

Examiner Initial	Desig. ID	Document
Y.P. 27		Anatomy of the Lumbar Spine in MED TM MicroEndoscopic Discectomy (1997 Ludann Grand
	28	Rapids MI) 14 pgs  Dirksheier et al. "Microendoscopic and Open Laminotomy and Discectomy in Lumbar Disc  Disease Seminars in Spine Surgery 1999 11(2): 138-146
	29	METRx Delivered Order Form 13 pages
	30	Medtronic Sofanor Danek "METRx <sup>TM</sup> MicroDisectomy System," Medtronic Sofamor Danek USA 2000, 21 pgs.
	31	Medtronic Sofamor Danek "METRx System Surgical Technique," 2004, 22 pages
	32	"MetRx System MicroEndoscopic Discectomy: An Evolution in Minimally Invasive Spine Surgery Sofamor Danek, 1999, 6 pages
	33	Smith and Foley "MetRx System MicroEndoscopic Discectomy: Surgical Technique" Medtronic Sofamor Danek, 2000, 24 pages
	34	"Sofamor Danek MED Microendoscopic Discectomy System Brochure" including Rapp "New endoscopic lumbar technique improves access preserves tissue" Reprinted with permission from: Orthopedics today 1998 18(1): 2 pgs
	35	Japanese Patent Office JP Patent Application No. 2006-528306 Office Action with English Translation dated June 10, 2009, 4 pages
	36	Plaintiffs' Preliminary Invalidity Contentions re US Patents 7207949; 7470236 and 7582058, dated September 18, 2009, 19 pages
	37	Plaintiffs' Preliminary Invalidity Contentions-Appendices September 18, 2009, 191 pages
	38	Plaintiffs' Supplemental Preliminary Invalidity Contentions re US Patents 7207949, 7470236, and 7582058, dated September 29, 2009, 21 pages
	39	Plaintiffs' Supplemental Preliminary Invalidity Contentions-Appendices dated September 29, 2009 294 pages
	40	Axon 501(k) Notification: Epoch 2000 Neurological Monitor, December 3, 1997, 464 pages
	41	Foley and Smith, "Microendoscopic Discectomy," Techniques in Neurosurgery, 1997, 3(4):301-30
	42	Medtronic Sofamor Danek "UNIONTM / UNION-LTM Anterior & Lateral Impacted Fusion Devices Clear choice of stabilization" Medtronic Sofamor Danek, 2000, 4 pages
43		NuVasive Vector <sup>™</sup> Cannulae, 1 page (prior to Sept. 25 2003)
	44	NuVasive Triad <sup>™</sup> Tri-Columnar Spinal EndoArthrodesis <sup>™</sup> via Minimally Invasive Guidance, 1 page (prior to Sept. 25 2003)
	45	NuVasive Triad <sup>™</sup> Cortical Bone Allograft, 1 page (prior to Sept. 25 2003)
xaminer Signa	ature / Y	OGESH PATEL/ Date Considered 01/14/2010

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Sheet <u>3</u> of <u>4</u>

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	Other D	ocuments (include Author, Title, Date, and Place of Publication)
Examiner Initial	Desig. !D	Document
Y.P.	46	NaVasive Vertebral Body Access System, 1 page (prior to Sept. 25 2003)
	47	Marina, "New Technology for Guided Navigation with Real Time Nerve Surveillance for Minimally Invasive Spine Discectomy & Arthrodesis," Spineline, 2000, page 39
	48	NuVasive UNS-1 Screw Test," 2001, 10 pages
	49	NuVasive letter re 510k Neuro Vision JJB System, dated October 16, 2001, 5 pages
	50	NuVasive letter re \$10k Guided Arthroscopy System, dated October 5, 1999, 6 pages
	51	NuVasive letter re 5 0k INS-1 Intraoperative Nerve Surveillance System, dated November 13, 2000, 7 pages
	52	"NuVasiveTM Receives Clearance to Market Two Key Elem Minimally Invasive Spine Surgery System," November 27, 2001, 20 pages
	53	Schick et al. "Microendoscopic lumbar discectomy versus open surgery: an intraoperative EMG study," Eur Spine J, 2002, 11: 2026
	54	NuVasive letter re: 510(k) for Neuro vision JJB System (Summary), September 25, 2001, 28 pages
manna	55	NuVasive letter re: Special 510(k) Premarket Notification: Neurovision JJB System (Device Description), July 3, 2003, 18 pages
	56	NuVasive letter re: Special 510(k) Premarke Notification: Neurovision JJB System (Device Description), March 1, 2004, 16 pages
	57	NuVasive letter re: Special 510(k) Premarket Notification: Neurovision JJB System (Device Description), May 26, 2005, 17 pages
	58	NuVasive letter re: 510(k) Premarket Notification: Neurovision JJB System (Device Description), June 24, 2005, 16 pages
	59	NuVasive letter re: Special 510(k) Premarket Notification: Neurovision JJB System (Device Description), September 14, 2006, 17 pages
	60	NuVasive 510(k) Premarket Notification: Neurovision JJB System (Device Description), August 20, 2007, 8 pages
	61	NuVasive letter re: 510(k) Premarket Notification: Guided Spinal Arthroscopy System (Device Description), February 1, 1999, 40 pages
	62	NuVasive 510(k) Premarket Notification: Spinal System (Summary), April 12, 2004, 10 pages
	63	NuVasive 510(k) Summary NIM Monitor, September 4, 1998, 4 pages
	64	NuVasive correspondence re 510(k) Premarket Notification INS-1 Intraoperative Nerve Surveillance System: Section IV Device Description," pages 12-51 (prior to Sept. 25 2003)
	65	NuVasive letter re 510(k) Premarket Notification INS-1 Intraoperative Nerve Surveillance System, August 24, 2000, 81 pages
	66	Isley et al., "Recent Advances in Intraoperative Neuromonitoring of Spinal Cord Function. Pedicle Screw Stimulation Techniques," <u>American Journal of Electroneurodagnostic Technology</u> , June 1997, 37(2): 93-126
V	67	Mathews et al., "Laparoscopic Discectomy with Anterior Lumbar Interbody Fusion," <u>SPINE</u> , 1995, 20(16): 1797-1802

Examiner Signature /YOGESH PATEL/	Date Considered 01/14/2010
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L			January 16, 2004	3132	

	Other Documents (include Author, Title, Date, and Place of Publication)					
Examiner Desig.						
Initial	ID	Document				
Rose et al., "Persistently Electrified Pedicle Stimulation Instruments in Spinal Instrumentation: Techniques and Protocol Development," SPINE, 1997, 22(3): 334-343		Rose et al., "Persistently Electrified Pedicle Stimulation Instruments in Spinal Instrumentation: Techniques and Protocol Development," SPINE, 1997, 22(3): 334-343				
	69 "Electromy ography System," <u>International Search report, International Application No.</u> PCT/US00/32329, (April 27, 2001), 9 pages					
70 "Nerve Proximity and Status Detection System and Method" International Search Report International Application No. PCT/US01/18606(Oct. 18 2001)6 pages.						
	71	"Relative Nerve Movement and States Detection System and Method" International Search Report International Application No. PCT/US01748579(Jan. 15 2002)6 pages.				
	72	"System and Method for Determining Nerve Proximity Direction and Pathology During Surgery"  International Search Report International Application No. PCT/US02/22247(Mar. 27 2003)4 pages.				
	73	"System and Methods for Determining Nerve Direction to a Surgical Instrument" International Search Report International Application No. PCT/US03/02056(Aug. 12 2003)5 pages.				
	74	"Systems and Methods for Performing Percutaneous Pedicle Integrity Assessments" International Search Report International Application No. PCT/US02/35047(Aug. 11 2003)5 pages.				
V	"Systems and Methods for Performing Surgery Procedures and Assessments" International Search Report International Application No. PCT/US02/30617(Jun. 5 2003)4 pages.					

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